United States Court of Appeals
For the Eighth Circuit

No. 12-3130

Carol Mack; Aaron Mack, wife and husband

Plaintiffs - Appellants

v.

Stryker Corporation, a Michigan corporation; Stryker Sales Corporation, a Michigan corporation

Defendants - Appellees

Appeal from United States District Court
for the District of Minnesota - Minneapolis

Submitted: October 24, 2013
Filed: May 12, 2014

Before BYE, SMITH, and BENTON, Circuit Judges.

SMITH, Circuit Judge.

Carol Mack underwent shoulder surgery in 2002. The surgeon inserted a pain pump designed to infuse anesthetic into Mack's shoulder to mitigate her pain while she recovered from surgery. Following surgery, Mack developed a painful shoulder condition known as chondrolysis. Mack, along with her husband, sued Stryker Corporation and Stryker Sales Corporation (collectively, "Stryker"), the manufacturer

and seller of the pain pump. Mack alleged negligence and strict products liability for design defect and failure to warn. Her husband asserted a claim for loss of consortium. The district court[1] granted Stryker's motion for summary judgment. On appeal, Mack contends that the district court misapplied the summary judgment standard by construing the facts in a light more favorable to Stryker. Furthermore, Mack contends that "[t]he district court . . . disregarded admissible expert testimony and instead relied upon the court's own inexpert interpretation of technical evidence and its relevance to conclude that there was no evidence that Stryker should have known of the risk to cartilage posed by its pain pump." We affirm.

I. *Background*

Mack underwent arthroscopic shoulder surgery on August 1, 2002, to alleviate persistent pain in her left shoulder. Near the surgery's conclusion, the surgeon inserted a pain pump that Stryker had manufactured, marketed, and sold to him. The pump consisted of a pumping mechanism and anesthetic reservoir attached to a catheter. The pain pump was designed to deliver a set dosage of an anesthetic, in this case bupivacaine, at regular intervals into a patient's surgically repaired shoulder for approximately two days to assist in the patient's recovery from surgery. Specifically, the pump was designed to inject bupivacaine directly into the glenohumeral joint space of the patient's shoulder. Stryker marketed its pain pumps for this use.

The glenohumeral joint consists of a ball (humeral head) and socket (the glenoid). During shoulder movement, the ball glides (articulates) against the socket. A layer of articular cartilage acts as a cushion by covering the ball and socket, thus preventing painful bone-on-bone contact during shoulder movement. Articular cartilage is found only in enclosed joint spaces like the glenohumeral joint. Articular cartilage is somewhat unique in that synovial fluid, not blood, nourishes the cartilage

[1]The Honorable Paul A. Magnuson, United States District Judge for the District of Minnesota.

cells. When these cartilage cells no longer receive nourishment from synovial fluid, they die. Eventually, the cartilage matrix comprised of these dead cells dissipates until no cartilage remains. When no cartilage remains, shoulder movement is accompanied by painful bone-on-bone contact where the ball and socket interact without the protective cushion. Chondrolysis is the painful medical condition whereby an individual loses articular cartilage in a joint.

Following her surgery, Mack began to experience additional shoulder pain. She began receiving additional treatment and therapy on the shoulder in 2003. By January 2004, Mack was diagnosed with chondrolysis. Mack underwent several additional shoulder surgeries to combat chondrolysis's effects.

Mack brought this diversity suit against Stryker on July 13, 2010. Mack asserted several theories of recovery, including negligence and strict products liability based on a design defect and failure to warn.[2] The district court granted Stryker's motion for summary judgment. *Mack v. Stryker Corp.*, 893 F. Supp. 2d 976, 978 (D. Minn. 2012). The district court reasoned that, based on the medical literature existing at the time of Mack's surgery in 2002, it was not reasonably foreseeable to Stryker that the use of its pain pump in an articular joint would lead to joint damage. *Id.* at 987. In fact, the medical community was unaware of any link between pain pumps and chondrolysis until at least 2007.[3] *Id.* The district court noted that it was "troubled by the hindsight and speculation necessary to find in favor of Mack." *Id.* The district

---

[2]Mack also asserted causes of action for fraud, negligent misrepresentation, and breach of warranties. Mack abandoned these causes of action prior to the district court's summary judgment determination.

[3]Other courts have determined that the medical community did not find a specific link between intra-articular use of pain pumps and chondrolysis until 2005. *See Rodriguez v. Stryker Corp.*, 680 F.3d 568, 570–71 (6th Cir. 2012). We need not determine the specific date of the medical community's discovery because the parties agree that it was years after Mack's surgery in 2002.

court added that "[t]he law does not obligate Stryker to be a pioneer, particularly when existing literature did not objectively forewarn of injury," *id.* at 987 (citation omitted), and "[i]t would be nothing short of rank speculation to suggest that any testing Stryker may have undertaken prior to 2002 would necessarily have revealed the causal connection that is still arguably unsettled today," *id.* at 988 (citation omitted).

II. *Discussion*

Mack contends on appeal that the district court erred by failing to recognize the extent of the medical community's knowledge of the risks associated with intra-articular pain pumps at the time of Mack's surgery. Mack also disputes the effect of the Food and Drug Administration's (FDA) failure to clear intra-articular pain pumps for postoperative use.

"We review de novo a district court's grant of summary judgment." *Rester v. Stephens Media, LLC*, 739 F.3d 1127, 1130 (8th Cir. 2014) (citation omitted). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "We view the facts in the light most favorable to the nonmoving party and give that party the benefit of all reasonable inferences that can be drawn from the record." *Spencer v. Jackson Cnty. Mo.*, 738 F.3d 907, 911 (8th Cir. 2013) (quotation, alteration, and citation omitted). The parties agree that Minnesota substantive law applies.

In Minnesota, a plaintiff who asserts a strict products liability claim must demonstrate "that (1) the product was in fact in a defective condition, unreasonably dangerous for its intended use; (2) such defect existed when the product left defendant's control; and (3) the defect was the proximate cause of the injury sustained." *Lee v. Crookston Coca-Cola Bottling Co.*, 188 N.W.2d 426, 432 (Minn. 1971). To recover on a negligence theory, the plaintiff must show "(1) the existence of a duty of care; (2) a breach of that duty; (3) an injury; and (4) the breach of the duty

being the proximate cause of the injury." *Schafer v. JLC Food Sys., Inc.*, 695 N.W.2d 570, 573 (Minn. 2005). The Supreme Court of Minnesota has stated that, in the design defect context, there is little or no distinction between strict liability and negligence. *See Lee*, 188 N.W.2d at 432 ("While in conventional tort terms no proof of negligence is necessary [in a strict products liability action], in many cases proof of a defect may simply be a substitute word for negligence."); *see also Piotrowski v. Southworth Prods. Corp.*, 15 F.3d 748, 751 (8th Cir. 1994) ("Where design defect cases are involved, Minnesota merges the theories of strict liability and negligence.") (citation omitted).

The Supreme Court of Minnesota has explained:

> A manufacturer is obligated to exercise that degree of care in his plan or design so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger when the product is used in the manner for which the product was intended, as well as an unintended yet reasonably foreseeable use.
>
> What constitutes "reasonable care" will, of course, vary with the surrounding circumstances and will involve a balancing of the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm.

Bilotta v. Kelley Co., Inc., 346 N.W.2d 616, 621 (Minn. 1984) (quotations, alteration, and citations omitted).

Drug and medical device manufacturers have "the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products." *O'Hare v. Merck & Co.*, 381 F.2d 286, 291 (8th Cir. 1967) (adjudicating a negligence claim under Minnesota law). They have a duty to test and investigate their products based upon the foreseeable risk of harm to potential users in light of current medical knowledge and discoveries. *Id.* Manufacturers are

held to the skill of an expert in the field that their products enter, and they are obligated to keep informed of medical knowledge and discoveries in that field. *Id.* Thus, "[t]he manufacturer is held accountable as an expert in its field only for those dangers of which it has knowledge or those which it could discover through the exercise of reasonable care." *Id.* (footnote omitted).

However, drug manufacturers are not insurers of the products that they sell. *Id.* at 290–91. Consequently, no liability attaches where the harmful effects of a product are those that no human skill or foresight could have predicted. *Id.* at 291. "The manufacturer's duty to warn users of the potential danger inherent in its product is commensurate with its actual knowledge of the risk involved to those users or the knowledge constructively imparted to it by available scientific or other medical data." *Id.*

According to Minnesota law, therefore, the foreseeability of potential harm determines the existence and extent of the manufacturer's duty to warn. *See id.*; *see also Whiteford by Whiteford v. Yamaha Motor Corp., U.S.A.*, 582 N.W.2d 916, 918 (Minn. 1998) ("In Minnesota, it is well settled that a manufacturer has a duty to protect users of its products from foreseeable dangers. But if the danger is not foreseeable, there is no duty.") (footnotes omitted). "In determining whether a danger is foreseeable, courts look at whether the specific danger was objectively reasonable to expect, not simply whether it was within the realm of any conceivable possibility." *Whiteford*, 582 N.W.2d at 918 (footnote omitted).

Finally, the Supreme Court of Minnesota has acknowledged that "[f]oreseeability of injury is a threshold issue related to duty that is ordinarily 'properly decided by the court prior to submitting the case to the jury.'" *Domagala v. Rolland*, 805 N.W.2d 14, 27 (Minn. 2011) (quoting *Alholm v. Wilt*, 394 N.W.2d 488, 491 n.5 (Minn. 1986)). The court submits the issue of foreseeability to the jury only "in close cases." *Domagala*, 805 N.W.2d at 27. Minnesota's foreseeability test "look[s]

to the defendant's conduct and ask[s] whether it was objectively reasonable to expect the specific danger causing the plaintiff's injury." *Id.* (citation omitted). However, "[t]he test is not whether the precise nature and manner of the plaintiff's injury was foreseeable, but whether the possibility of an accident was clear to the person of ordinary prudence." *Id.* (quotation and citations omitted).

A. Medical Literature

To establish that the use of pain pumps in articular joints presented a foreseeable risk of harm at the time of Mack's surgery, Mack provided the expert testimony of Dr. Stephen Trippel, an orthopedic surgeon who specializes in the study of articular cartilage. In his declaration, Dr. Trippel opined that "[l]ong before 2000, existing medical and scientific knowledge of the anatomy and physiology of joint spaces and intra-articular cartilage indicated that continuous exposure to foreign [s]olutions could be harmful to the articular cartilage." He further stated:

> Prior to 2000, what was known by medical science about joints and the fragility of cartilage would have put a careful and prudent and reasonable medical device maker on notice that continuous infusion of commonly used anesthetics over a period of two to three days into a joint space would likely risk injury to the cartilage. There was enough information available, even before studies investigating the effect of irrigation solutions and local anesthetics on articular cartilage, to raise serious concern that there would likely be a problem if the articular cartilage were continually exposed to these substances for two to three days.

Stryker moved to exclude Dr. Trippel's testimony, arguing that his "opinion [that] Stryker was on notice that continuous infusion of local anesthetics into the intra-articular space was likely unsafe is unreliable because his own reliance literature does not support his opinion." In granting Stryker's motion for summary judgment, the district court denied as moot Stryker's motion to exclude Dr. Trippel's testimony. The district court agreed with Stryker that the medical literature at the time of Mack's

surgery "d[id] not support the conclusion that in 2002 Stryker should have known that its pain pump could ca[u]se cartilage damage." *Mack*, 893 F. Supp. 2d at 987. Consequently, we must determine whether the district court correctly concluded that the existing medical literature in 2002 was insufficient to allow Stryker to foresee the risk of articular cartilage damage from the use of its pain pumps for infusion of intra-articular anesthetics.

To support his opinion, Dr. Trippel relied on 12 medical articles that were published prior to Mack's surgery. The first article detailed a study whereby the researcher injected substances into rabbit joints to determine the effects of joint injections. *See* J. Albert Key, *The Production of Chronic Arthritis by the Injection of Weak Acids, Alkalies, Distilled Water, and Salt Solution into Joints*, 15 J. Bone & Joint Surgery 67, 84 (1933). After explaining the study's experimental design, Dr. Trippel relayed the researcher's findings "that in all cases, that is for all of the[] solutions, even the regular saline, the injections led to the rabbits getting arthritis in their knees." Furthermore, the severity of the arthritis correlated with the number of injections into the joint. Dr. Trippel extrapolated these conclusions to device manufacturers by noting that "[a]ny manufacturer reading this study would know that continuous injection into a joint for two to three days could risk harm to the cartilage."

The second article that Dr. Trippel relied upon for his opinion was similar to the Key article in that researchers determined that saline solution harmed cartilage. *See* Brian F. Reagan et al., *Irrigating Solutions for Arthroscopy, A Metabolic Study*, 65 J. Bone & Joint Surgery 629 (1983). Dr. Trippel explained the researchers' findings "that normal saline concentrations when given for one, two, five and eight hours was inhibitory to cartilage health." Dr. Trippel also stated that "[t]he time-and-dose response addressed in this article showed that the longer the cartilage was exposed to the saline, the worse the effect on the cartilage cells could be."

Dr. Trippel also relied on an article whereby researchers studied the effect of inundating articular cartilage from pigs and dogs with bupivacaine for up to two hours. *See* Roberta Nole et al., *Bupivacaine and Saline Effects on Articular Cartilage*, 1 Arthroscopy 123, 126 (1985). Dr. Trippel noted that the researchers found that bupivicaine inhibited cartilage cells; however, articular cartilage cells recovered from a maximum two-hour exposure within three days. The fourth article upon which Dr. Trippel relied was a literature review whereby the authors stated that, based on the Nole article, little was known about the long-term effects of the acute inhibition of articular cartilage cells. *See* John P. Fulkerson & Thomas F. Winters, Jr., *Articular Cartilage Response to Arthroscopic Surgery: A Review of Current Knowledge*, 2 Arthroscopy 184 (1986). The Fulkerson article contained no new findings.

Dr. Trippel also relied on an article detailing a study wherein researchers repeatedly injected rabbit joints with saline solutions and determined that repeated injections of saline over four weeks inhibited the synthesis of a vital protein used to generate cartilage cells. *See* J. Neidel et al., *Intra-articular Injections and Articular Cartilage Metabolism: An Experimental Study in Rabbits*, 111 Archives of Orthopaedic and Trauma Surgery 237 (1992). The study concluded that prolonged exposure to the saline solution prevented the cartilage from ever recovering.

The sixth study upon which Dr. Trippel relied showed how cartilage exposure to various solutions, none of which were anesthetics, over periods of two, four, and twenty hours demonstrated a "softening effect" upon the cartilage, indicating cartilage damage. *See* J.S. Jurvelin et al., *Effects of Different Irrigation Liquids and Times on Articular Cartilage: An Experimental, Biomechanical Study*, 10 Arthroscopy 667 (1994). Next, Dr. Trippel relied on a study in which researchers immersed the knee joints of rats into various solutions to determine the effect of these solutions on articular cartilage. *See* S.K. Bulstra et al., *The Effect In Vitro of Irrigating Solutions on Intact Rat Articular Cartilage*, 76–B Journal of Bone & Joint Surgery 468 (1994).

Dr. Trippel averred that the study demonstrates that a variety of substances harm articular cartilage upon contact.

The eighth article upon which Dr. Trippel relied involved the testing of morphine (a different anesthetic) on human articular cartilage. *See* John W. Jaureguito et al., *The Effects of Morphine on Human Articular Cartilage of the Knee: An In Vitro Study*, 18 Arthroscopy 631 (2002). The researchers in this article used saline solutions, saline solutions mixed with different concentrations of morphine, and combinations of morphine and bupivacaine.

The ninth and tenth articles upon which Dr. Trippel relied contained case reports regarding patients who lost cartilage in their shoulders following surgery. *See* Y. Shibata et al., *Chondrolysis of the Glenohumeral Joint Following a Color Test Using Gentian Violet*, 25 International Orthopedics 401 (2001); Kazuya Tamai et al., *Chondrolysis of the Shoulder Following a "Color Test"—Assisted Rotator Cuff Repair—A Report of 2 Cases*, 68 Acta Orthopaedica Scandinavica 401 (1997). The cartilage loss resulted from direct injection of gentian violet (a dye) into the glenohumeral joint.

The penultimate article upon which Dr. Trippel relied detailed six reports where patients' knees were accidentally irrigated with chlorhexidine 1% in aqueous solution during arthroscopy. *See* C.M. Douw et al., *Clinical and Pathological Changes in the Knee After Accidental Chlorhexidine Irrigation During Arthroscopy. Case Reports and Review of the Literature*, 80–B The Journal of Bone and Joint Surgery 437 (1998). All six patients developed chondrolysis in the knee. Similarly, the last article upon which Dr. Trippel relied described three patients who developed chondrolysis after receiving 0.02% aqueous chlorhexidine solution during arthroscopic knee surgery. *See* A.L. Van Huyssteen & D.J. Bracey, *Chlorhexidine and Chondrolysis in the Knee*, 81–B Journal of Joint and Bone Surgery 995 (1999). Dr. Trippel used this

study to demonstrate that joint exposure to low concentrations of chlorhexidine can cause extensive damage to articular cartilage.

Mack contends that the district court "failed to understand and analyze the literature" that supported Dr. Trippel's conclusion that pain pump manufacturers like Stryker should have known about potential risks inherent in continuously infusing any type of solution into articular joints. Stryker responds by noting that even Dr. Trippel admitted that the medical community had not drawn a connection between continuous infusion of a local anesthetic into an intra-articular joint and chondrolysis until 2005 or 2007. The question thus becomes whether the 12 articles support Dr. Trippel's opinions such that a jury should determine whether a device manufacturer could reasonably foresee that continuous infusion of bupivacaine into Mack's glenohumeral joint would harm her articular cartilage, notwithstanding that the medical community did not discern chondrolysis specifically as a risk until years after Mack's surgery.

We agree with the district court that the 12 articles underpinning Dr. Trippel's opinions do not support his conclusions. As the district court recognized, most of the articles that Dr. Trippel cites do not involve the study of the effects of continuous infusion of bupivacaine or other anesthetics in articular joints. *See Mack*, 893 F. Supp. 2d at 986. The Key, Reagan, Jurvelin, Bulstra, and Neidel articles involve the injection of saline solutions rather than anesthetics, so the manufacturer of a device designed to infuse anesthetics into the articular joint would have no reason to conclude that anesthetic infusion could harm the joint based on these articles. *See id.* The same problem arises with the Tamai and Shibata articles (gentian dye) and the Douw and Van Huyssteen articles (antiseptic chlorhexidine). *See id.*

The remaining articles, which involved the study of anesthetics, also fail to alert reasonable manufacturers like Stryker to the dangers of continuous infusion of bupivacaine into articular joints. For example, the conclusions of the Nole article directly conflict with Dr. Trippel's opinions. The Nole article would not alert a

reasonable medical device manufacturer like Stryker of the risk of its pain pumps. The district court explained that Nole concluded that "b[u]p[i]vacaine itself seems to be fairly well tolerated by articular cartilage, but the saline solution in which it is prepared is transiently inhibitory of the uptake of sulfates in articular cartilage." *Mack*, 893 F. Supp. 2d at 986 (quoting Nole, *supra*, at 126). Furthermore, "Nole also concluded that there was '[no] immediate need to stop the use of intraarticular bupivacaine.'" *Id.* (alteration in original) (quoting Nole, *supra*, at 126). Finally, the district court stated that "Nole further reported that affected cells recovered after three days, thereby suggesting that any impact was fleeting and reversible." *Id.* (citing Nole, *supra*, at 126). Consequently, even careful study of the Nole article would fail to alert pain pump manufacturers of the dangers that Dr. Trippel asserts.

The Jaureguito article contains similar assurances, for it stated that solutions containing bupivacaine and morphine had no "'deleterious effect' on human articular cartilage." *Id.* (quoting Jaureguito, *supra*, at 635). As the district court noted, the Jaureguito article was also distinguishable because it involved older patients with advanced osteoarthritis. *Id.* at 982. Thus, the Jaureguito article also fails to alert Stryker to a foreseeable risk of harm to articular cartilage.[4]

Furthermore, the articles that Dr. Trippel identifies fail to capture the full context of the relevant medical knowledge at the time of Mack's surgery. First, surgeons have used "pain pumps to provide anesthetics to post-operative joints for years." *Rodriguez*, 680 F.3d at 570. Second, Stryker provides several articles that recognize the safety and effectiveness of placing pain pumps in articular joints. *See, e.g.*, Barber et al., *The Effectiveness of an Anesthetic Continuous–Infusion Device on*

[4]Additionally, the Jaureguito study was published only one month before Mack's surgery. *Id.* at 986 n.9. Because we conclude that it would not have provided Stryker with notice of potential harm, we need not decide whether publication of an article one month before a patient's surgery gives a medical device manufacturer enough time to read, understand, and adapt to the article's findings.

Postoperative Pain Control, 18 Arthroscopy 76 (2002); Narinder Rawal et al., *Postoperative Patient-Controlled Local Anesthetic Administration at Home*, 86 Anesthesia & Analgesia 86 (1997). In one study, researchers set out "to examine the effectiveness of an intra-articular pain catheter for controlling postoperative pain following arthroscopic" surgery. Ken Yamaguchi et al., *Postoperative Pain Control Following Arthroscopic Release of Adhesive Capsulitis: A Short-Term Retrospective Review Study of the Use of an Intra-Articular Pain Catheter*, 18 The Journal of Arthroscopic and Related Surgery 359, 360 (2002). The researchers studied 20 patients who received continuous infusion of bupivacaine in their articular joints. *Id.* at 361–62. Out of 20 patients, only one patient experienced any complication from use of the pain pump—a temporary complication unrelated to chondrolysis. *Id.* at 363. The article concluded that "[t]he results of this study suggest that delivery of bupivacaine through an indwelling intra-articular pain catheter can be a highly effective means of achieving pain control following arthroscopic" surgery, especially where "[t]here were no direct complications with this method, including no infections." *Id.* at 364.

Our decision today is consistent with the Sixth Circuit's decision in *Rodriguez*. Like the district court here, the *Rodriguez* court considered Dr. Trippel's opinions and the bases for them, which included the same 12 articles that Dr. Trippel presented in the present case. *Id.* at 570–71.[5] The *Rodriguez* court adopted the reasoning of the district court from which Rodriguez appealed, which stated:

> While the pre-2004 medical articles raise the general notion that health of (usually animal) cartilage could be weakened by prolonged exposure to certain "foreign elements," it is a bridge way too far to say that Stryker—in the context in which infusion pumps were broadly used and medically accepted without reservation—should have, prior to marketing

[5]In fact, Dr. Trippel relied on a thirteenth study in *Rodriguez* because Rodriguez underwent shoulder surgery in 2004.

> the pain pump, culled through seven decades of literature, found the sporadic articles raising this concern, ignored all the authority/evidence to the contrary, and then independently concluded that its pain pump could cause chondrolysis, particularly where no one in the medical community connected the destruction of cartilage to the use of pain pumps until after the plaintiff's surgery.

Id. at 573. We agree.[6] The 12 articles that Dr. Trippel submits do not warn against the continuous infusion of bupivacaine in articular joints. Furthermore, other articles trumpeted the use of bupivacaine-injecting pain pumps into articular spaces. *See, e.g.*, Yamaguchi, *supra*, at 364. Mack fails to show that any "specific danger was objectively reasonable to expect"; therefore, we hold that Mack has demonstrated merely that articular cartilage damage "was within the realm of any conceivable possibility." *See Whiteford*, 582 N.W.2d at 918. "[N]o developed human skill or foresight" could have led a medical device manufacturer to select Dr. Trippel's articles, read them between the lines, ignore their conclusions, and ignore the plethora of other articles that recommended to the contrary. *See O'Hare*, 381 F.2d at 291 (quotation and citation omitted). Consequently, we conclude that Stryker could not have foreseen the potential for articular cartilage damage as the result of the surgical implementation of its pain pump based on the medical community's knowledge in

---

[6]A separate panel of the Sixth Circuit decided a similar case to *Rodriguez* less than three months later, and it reversed a district court's decision to grant summary judgment to a pain pump manufacturer without acknowledging *Rodriguez*. *See Krumpelbeck v. Breg, Inc.*, 491 F. App'x 713 (6th Cir. 2012) (unpublished). *Krumpelbeck* and *Rodriguez* directly conflict. We decline to consider *Krumpelbeck* because it is not the law of this circuit and likely not the law of the Sixth Circuit due to *Rodriguez's* prior publication. *See Rutherford v. Columbia Gas*, 575 F.3d 616, 619 (6th Cir. 2009) ("A published prior panel decision remains controlling authority unless an inconsistent decision of the United States Supreme Court requires modification of the decision or this Court sitting en banc overrules the prior decision." (quotation and citation omitted)). Additionally, we do not find it persuasive.

2002. Stryker, as a matter of law, had no duty to protect or warn Mack of the harm that Stryker's pain pumps may inflict. *See Domagala*, 805 N.W.2d at 27.

B. *FDA Denial*

Stryker and its predecessors in interest sought FDA approval for the use of pain pumps in the late 1990s. Typically, a company has two avenues by which to obtain FDA approval. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477–79 (1996). First, the company could pursue the more rigorous premarket approval (PMA) process whereby the FDA scrupulously evaluates the device's safety and effectiveness. *See id.* at 477. To avoid the costly, time-consuming PMA process, device manufacturers can seek clearance by providing "premarket notification" to the FDA. *Id.* at 478. Known as the "§ 510(k)"[7] process, the FDA would then approve a device if the manufacturer demonstrates that a "substantially similar" product is currently in use for that purpose. *See id.* at 478–79.

Stryker obtained § 510(k) clearance for its pain pump for "intraoperative" use; the parties agree that "intraoperative use" generally means a location on the body where surgery is performed. However, Stryker twice sought § 510(k) clearance for use of its pain pump in articular spaces, yet the FDA denied § 510(k) clearance on both occasions. These denials occurred before Mack's surgery. The FDA denied clearance because of the lack of a "substantially similar" predicate device. As the district court noted, Mack does not contend that the FDA denials alone subject Stryker to liability. *Mack*, 893 F. Supp. 2d at 985. Furthermore, Mack presents no evidence that the FDA denied Stryker's applications because of safety concerns or that Stryker violated any FDA regulation. *Id.* at 985–86. Mack contended before the district court that the FDA denials should have prompted Stryker to conduct safety tests on its pain pumps. *Id.* at 986. The district court rejected Mack's argument, stating that "[i]t would be illogical

[7]The "510(k)" process is named after the section number given to this process in the Medical Device Amendments of 1976.

to conclude that the FDA denial, which was not based on safety concern, and did not raise a safety concern within Stryker, triggered to duty to undertake safety testing or to warn of safety concerns." *Mack*, 893 F. Supp. 2d at 986.

On appeal, Mack avers that "the FDA denials told Stryker [ ] that it was not permitted to market pain pumps for intra-articular use because nobody had proven that such use was safe." Additionally, Mack contends that a denial of clearance based on the lack of a predicate device implicates safety because "a predicate device is a device that has been shown to be *safe and effective* for the intended use."

The Supreme Court has already rejected such arguments. *See Medtronic*, 518 U.S. at 492–93. The *Medtronic* Court explained that, pursuant to the § 510(k) process, medical device manufacturers must demonstrate that their devices are substantially equivalent to devices that were on the market before Congress passed the Medical Device Amendments of 1976. *Id.* at 477–78. Congress enacted this exception because several pre-1976 devices were grandfathered into the market such that they need not obtain PMA approval. *Id.* Thus, the § 510(k) exception exists to prevent these manufacturers from monopolizing the market while new devices cleared PMA and to ensure that improvements to existing devices could be introduced into the market quickly. *Id.* at 478. Because § 510(k) allows more recent devices to be grandfathered into the market without undergoing the PMA process, § 510(k) is concerned with "equivalence, not safety." *Id.* at 493 (citation omitted). The § 510(k) process protects the public little. *Id.* Post *Medtronic*, § 510(k) rejections typically do not alert device manufacturers that their products are unsafe.

Medtronic applies here. The FDA denials did not indicate to Stryker that use of its pain pumps in intra-articular spaces was unsafe or could result in foreseeable harm.

III. *Conclusion*

Therefore, we affirm the district court's decision to grant summary judgment to Stryker.

BYE, Circuit Judge, dissenting.

I believe Carol Mack is entitled to have a jury determine whether the use of pain pumps in articular joints presented a foreseeable risk of harm at the time of her August 2002 shoulder surgery. I therefore respectfully dissent.

As the court acknowledges, the issue of foreseeability under Minnesota law is reserved for the jury's determination in "close cases." Ante at 6 (quoting Domagala v. Rolland, 805 N.W.2d 14, 27 (Minn. 2011)). In Huggins v. Stryker Corp., 932 F. Supp. 2d 972 (D. Minn. 2013), a federal district court addressed a similar claim involving a February 2002 surgery date and determined "a jury could reasonably find by a preponderance of the evidence that Stryker should have known the risks of intra-articular pain pump use [in February 2002]." Id. at 990. In denying Stryker's motion for summary judgment, the court noted that Minnesota requires the issue of foreseeability to be submitted to the jury in "close cases." Id. at 986.

Significantly, the medical literature at issue in Huggins is essentially the same medical literature at issue in this case. See id. at 978-79 & n.4 (involving ten of the same twelve published studies dating between 1933 and 1999 which were relied upon by Mack's experts). The district court indicated cases "across the country" have addressed whether pain pump manufacturers such as Stryker knew or should have known intra-articular pain pump use could cause cartilage damage based on the existing medical literature, and noted the courts "have confronted this issue with inconsistent results." Id. at 986-87 (citing cases where summary judgment has been both granted and denied). In addition to Huggins, summary judgment has been denied in several cases involving surgery dates comparable to Mack's August 2002 surgery.

See Hackett v. Breg, Inc., Civ. No. 10-1437, 2011 WL 4550186, at *1 (D. Colo. Oct. 3, 2011) (involving an April 3, 2002, surgery date); Creech v. Stryker Corp., No. 2:07CV22 DAK, 2012 WL 33360 at *1 (D. Utah Jan. 6, 2012) (involving six surgeries between February 2003 and July 2004); Kildow v. Breg, Inc., 796 F. Supp. 2d 1295, 1298 (D. Or. 2011) (involving surgeries in July 2003 and March 2004).[8] Huggins also noted "multiple juries have found that the risks were foreseeable" when the jury was allowed to consider the issue. See Huggins, 932 F. Supp. 2d at 987 (citing the final judgment in Hackett, and Beale v. I-Flow Corp., No. 0801-01554 (Ore. Cir. Ct. Multnomah Cnty. Dist. Jan. 22, 2010)).

Given the inconsistent decisions reached on the issue of foreseeability by both reasonable judges and reasonable jurors, I fail to see how we can conclude Mack's claim on foreseeability is anything but a "close case." Minnesota law thus allows her to have a jury decide her claim. I therefore disagree with our decision to affirm the grant of summary judgment in favor of Stryker. I would reverse the district court and remand this "close case" for a jury trial.

---

[8]The slight difference in surgery dates is immaterial where the majority of the medical literature at issue was published by 1999.